

Applicants: Daniella Licht et al.
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Page 2

Amendments to the Claims

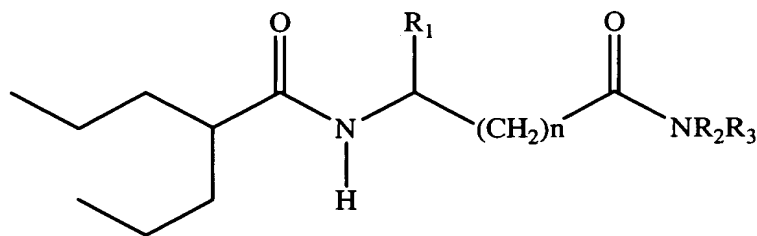
Please cancel claims 56-71 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in this or a related application.

Please amend claims 3, 4, 13, 15, 34 and 38-46 under the provisions of 37 C.F.R. §1.121, as set forth in the Federal Register on June 30, 2003 as follows:

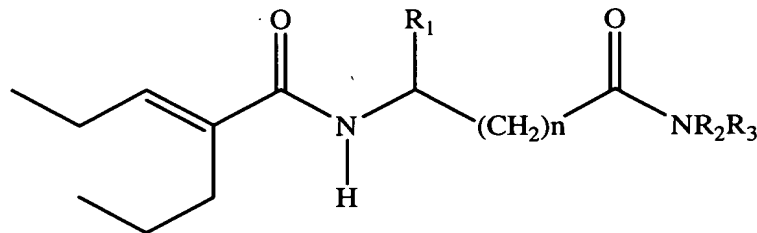
1. (Original) An immediate release solid dosage form comprising the following components:

a) a uniform admixture of:

- (i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:



or



wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a C_1 - C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

- (ii) a hydroxypropyl cellulose, and

b) a disintegrant.

2. (Original) The solid dosage form of claim 1, wherein the solid dosage form is a tablet.
3. (Currently Amended) The solid dosage form of claim 1 ~~er~~—2, wherein the uniform admixture of component a) further comprises a filler.
4. (Currently Amended) The solid dosage form of claim 1 ~~er~~—2, wherein the solid dosage form further comprises a filler and a lubricant as additional components.
5. (Original) The solid dosage form of claim 3, wherein the filler of component a) comprises a microcrystalline cellulose, lactose, a starch, or a combination of two or more of the foregoing.
6. (Original) The solid dosage form of claim 5, wherein the filler of component a) comprises a microcrystalline cellulose.
7. (Original) The solid dosage form of claim 4, wherein the additional filler comprises a microcrystalline cellulose, lactose, a starch, or a combination of two or more of the foregoing.
8. (Original) The solid dosage form of claim 7, wherein the filler comprises a microcrystalline cellulose.
9. (Original) The solid dosage form of claim 7, wherein the filler comprises lactose.

10. (Original) The solid dosage form of claim 4, wherein the lubricant comprises magnesium stearate, sodium stearyl fumarate, hydrogenated castor oil, hydrogenated soybean oil, polyethylene glycol or a combination of two or more of the foregoing.
11. (Original) The solid dosage form of claim 10, wherein the lubricant comprises magnesium stearate.
12. (Original) The solid dosage form of claim 10, wherein the lubricant comprises sodium stearyl fumarate.
13. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, wherein the disintegrant of component b) is croscarmellose sodium, sodium starch glycolate or a combination thereof.
14. (Original) The solid dosage form of claim 13, wherein the disintegrant of component b) is croscarmellose sodium.
15. (Currently Amended) The solid dosage form of claim 1 ~~or 2~~, wherein the active ingredient of component a) is selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide,
N-(2-Propylpentanoyl)glycinamide,
N-(2-propylpentanoyl)glycine-N'-methanamide,
N-(2-propylpentanoyl) glycine-N'-butylamide,
N-(2-propylpentanoyl)leucinamide,

N-(2-propylpentanoyl)alanine-N'-benzylamide,
N-(2-propylpentanoyl)alapinamide,
N-(2-propylpentanoyl)-2-phenylglycinamide,
N-(2-propylpentanoyl)threoninamide,
N-(2-propylpentanoyl)glycine-N',N'-dimethylamide,
N-(2-propylpent-2-enoyl)glycinamide,
N-(2-propylpent-2-enoyl)alaninamide, and
N-(2-propylpent-2-enoyl)glycine-N'-methylamide.

16. (Original) An immediate release tablet comprising the following components:
 - a) a uniform admixture of:
 - (i) N-(2-Propylpentanoyl)glycinamide; and
 - (ii) a hydroxypropyl cellulose; and
 - b) a disintegrant.
17. (Original) The tablet of claim 16, wherein the uniform admixture of component a) further comprises a filler, and the tablet further comprises a filler and a lubricant as additional components.
18. (Original) The tablet of claim 17, wherein the filler of component a) comprises a microcrystalline cellulose, lactose, a starch, or a combination of two or more of the foregoing.
19. (Original) The tablet of claim 18, wherein the filler of component a) comprises a microcrystalline cellulose.
20. (Original) The tablet of claim 18, wherein the additional filler comprises a microcrystalline

cellulose, lactose, a starch, or a combination of two or more of the foregoing.

21. (Original) The tablet of claim 20, wherein the additional filler comprises a microcrystalline cellulose.
22. (Original) The tablet of claim 20, wherein the additional filler comprises lactose.
23. (Original) The tablet of claim 17, wherein the lubricant comprises magnesium stearate, sodium stearyl fumarate, hydrogenated castor oil, hydrogenated soybean oil, polyethylene glycol or a combination of two or more of the foregoing.
24. (Original) The tablet of claim 23, wherein the lubricant comprises magnesium stearate.
25. (Original) The tablet of claim 23, wherein the lubricant comprises sodium stearyl fumarate.
26. (Original) The tablet of claim 16, wherein the disintegrant of component b) is croscarmellose sodium, sodium starch glycolate or a combination thereof.
27. (Original) The tablet of claim 26, wherein the disintegrant of component b) is croscarmellose sodium.

28. (Original) The tablet of claim 16 comprising the following components:
- a) a uniform admixture of
 - from 50 mg/tablet to 1000 mg/tablet N-(2-Propylpentanoyl)glycinamide; and
 - from 5 mg/tablet to 150 mg/tablet hydroxypropyl cellulose; and
 - b) from 1 mg/tablet to 100 mg/tablet croscarmellose sodium.
29. (Original) The tablet of claim 28, wherein component a) further comprises from 1 mg/tablet to 300 mg/tablet microcrystalline cellulose as an additional component.
30. (Original) The tablet of claim 29, wherein the tablet further comprises
 - from 5 mg/tablet to 500 mg/tablet filler; and
 - from 0.1 mg/tablet to 20 mg/tablet lubricant.
31. (Original) The tablet of claim 16 comprising the following components:
- a) a uniform admixture of
 - from 250 mg/tablet to 500 mg/tablet N-(2-Propylpentanoyl)glycinamide; and
 - from 25 mg/tablet to 50 mg/tablet hydroxypropyl cellulose; and
 - b) from 40 mg/tablet to 60 mg/tablet croscarmellose sodium.
32. (Original) The tablet of claim 31, wherein component a) further comprises from about 50 mg/tablet to

about 100 mg/tablet microcrystalline cellulose as an additional component.

33. (Original) The tablet of claim 32, wherein the tablet further comprises
from 100 mg/tablet to 500 mg/tablet filler; and
from 2 mg/tablet to 20 mg/tablet lubricant.

34. (Currently Amended) The tablet of ~~claim 30 or 33~~
claim 33, wherein
the additional filler comprises lactose,
microcrystalline cellulose, mannitol or a
combination of two or more of the foregoing; and
the lubricant of component b) is magnesium
stearate or sodium stearyl fumarate or a
combination thereof.

35. (Original) The tablet of claim 34 comprising the following components:
a) a uniform admixture of
500 mg/tablet N-(2-Propylpentanoyl)
glycinamide;
50 mg/tablet hydroxypropyl cellulose; and
100 mg/tablet a microcrystalline cellulose, and
b) 55 mg/tablet croscarmellose sodium;
145 mg/tablet lactose; and
6 mg/tablet magnesium stearate.

36. (Original) The tablet of claim 34 comprising the following components:
a) a uniform admixture of

500 mg/tablet N-(2-Propylpentanoyl)
glycinamide;
50 mg/tablet hydroxypropyl cellulose; and
100 mg/tablet a microcrystalline cellulose, and
b) 50 mg/tablet croscarmellose sodium;
145 mg/tablet lactose; and
6 mg/tablet magnesium stearate.

37. (Original) The tablet of claim 34, comprising

a) a uniform admixture of:
250 mg/tablet N-(2-Propylpentanoyl)
glycinamide;
25 mg/tablet hydroxypropyl cellulose; and
50 mg/tablet microcrystalline cellulose;
b) 450 mg/tablet microcrystalline cellulose;
50 mg/tablet croscarmellose sodium; and
6 mg/tablet magnesium stearate.

38. (Currently Amended) A method of treating neuropathic pain in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby treat the neuropathic pain in the subject.

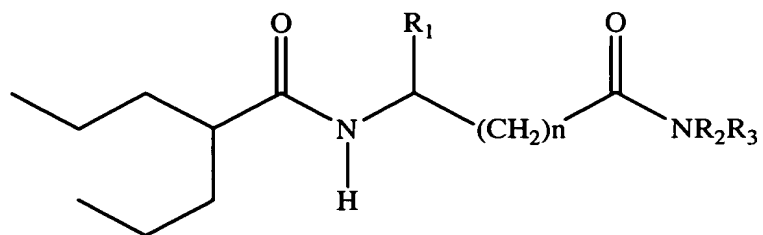
39. (Currently Amended) A method of treating a headache disorder in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any~~

~~one of claims 16-37~~ claim 1 in order to thereby treat the headache disorder in the subject.

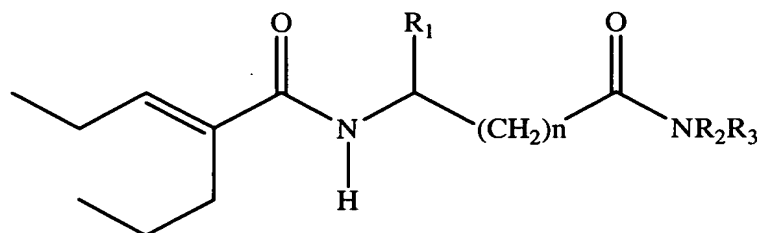
40. (Currently Amended) A method of treating epilepsy in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby treat epilepsy in the subject.
41. (Currently Amended) A method of controlling seizures in a subject suffering from epilepsy comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby control the seizures in the subject.
42. (Currently Amended) A method of treating pain in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby treat pain in the subject.
43. (Currently Amended) A method of pain prophylaxis in a subject in need of such treatment comprising administering to the subject a prophylactic dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in

order to thereby effect pain prophylaxis in the subject.

44. (Currently Amended) A method of treating mania in bipolar disorder in a subject in need of such treatment comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby treat mania in bipolar disorder in the subject.
45. (Currently Amended) A method of attenuating bipolar mood swings in a subject suffering from bipolar disorder comprising administering to the subject a therapeutically effective dose of the solid dosage form of ~~any one of claims 1-15 or the tablet of any one of claims 16-37~~ claim 1 in order to thereby attenuate the bipolar mood swings in the subject.
46. (Currently Amended) A process for preparing the solid dosage form of claim 1 ~~or 2~~, comprising the steps of:
- a) admixing predetermined amounts of
 - (i) an active ingredient selected from the group consisting of valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide and a compound having the structure:



or



wherein R_1 , R_2 , and R_3 are independently the same or different and are hydrogen, a $\text{C}_1\text{-C}_6$ alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3; and

(ii) a hydroxypropyl cellulose;

b) admixing the uniform mixture of step a) with a predetermined amount of a disintegrant; and
c) compressing the mixture of step b) to form the tablet.

47. (Original) The process of claim 46, wherein step b) further comprises admixing the uniform mixture with predetermined amounts of a filler and a lubricant.

48. (Original) The process of claim 47, wherein the filler of step b) is microcrystalline cellulose,

anhydrous dicalcium phosphate, lactose or a combination of two or more of the foregoing.

49. (Original) The process of claim 48, wherein the filler is lactose.

50. (Original) The process of claim 48, wherein the filler is a microcrystalline cellulose.

51. (Original) The process of claim 47, wherein the lubricant is magnesium stearate or sodium stearyl fumarate or a combination thereof.

52. (Original) The process of claim 51, wherein the lubricant is magnesium stearate.

53. (Original) The process of claim 51, wherein the lubricant is sodium stearyl fumarate.

54. (Original) The process of claim 47, wherein the disintegrant of step b) is croscarmellose sodium, sodium starch glycolate or a combination thereof.

55. (Original) The process of claim 54, wherein the disintegrant of step b) is croscarmellose sodium.

Claims 56-71. (Canceled)